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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/724,564	11/26/2003	Wayne Edward Beimesch	414130	9670
30954	7590	05/30/2006		
LATHROP & GAGE LC 2345 GRAND AVENUE SUITE 2800 KANSAS CITY, MO 64108			EXAMINER ROGERS, DAVID A	
			ART UNIT 2856	PAPER NUMBER

DATE MAILED: 05/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/724,564		BEIMESCH, WAYNE EDWARD	
	Examiner		Art Unit	
	David A. Rogers		2856	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 23-34 are rejected under 35 U.S.C. 102(b) as being anticipated by United States Patent 4,930,906 to Hemphill.

Claims 23-31 recite two elements that form the kit, namely an enclosed bag that is sealable to produce a headspace and a list of instructions for how to use the sealable bag. In this regard Hemphill teaches an enclosed bag (reference item 10) and having instructions (reference items 18 and 20). The enclosed bag also has a maximum fill line (reference item 19). This bag, when sealed, would have a headspace above the maximum fill line. In claims 32-34 the applicant's bag is further limited to having an inner aluminum layer and an outer polymeric layer. As seen in figure 5 the bag of Hemphill comprises an aluminum inner layer (reference item 13) and a polymeric intermediate layer (reference item 11). The intermediate layer is disposed on the outside of the inner aluminum layer thus it is an "outside" layer. Furthermore, the applicant's claims use the open-ended term "comprising" thus allowing for any number of layers to be disposed on the polymeric layer. Therefore, Hemphill

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teaches a kit that meets the structural limitations of the applicant's claims. Hemphill does not teach specific instructions with regard to sampling and analyzing.

In their precedential decision *In re Ngai*, 70 USPQ 2d 1862, the Court of Appeals for the Federal Circuit (CAFC) reviewed a situation clearly analogous to the applicant's claims. In *Ngai et al.* a kit was claimed as follows (emphasis added):

19. A kit for normalizing and amplifying an RNA population, *said kit comprising instructions describing the method of claim 1 and a premeasured portion of a reagent selected from the group consisting of:* oligo dT biotinylated primer, T7 RNA polymerase, annealed biotinylated primers, streptavidin beads, polyadenyl transferase, reverse transcriptase, Rnase H, DNA pol I, *buffers* and nucleotides.

The CAFC analyzed *Ngai et al.*'s claim 19 and determined that the elements that formed the kit included a premeasured portion of reagent and instructions on how to use the reagent. The cited prior art was a kit having a 10X buffer and specific instructions on how to use the 10X buffer. In referring to *In re Gulack*, 703 F.2d 1381 [217 USPQ 401] (Fed. Cir. 1983), the CAFC stated:

"This case [*Ngai*], however, is dissimilar from *Gulack*. There the printed matter and the circularity of the band were interrelated, so as to produce a new product useful for "educational and recreational mathematical" purposes. Here, addition of a new set of instructions into a known kit does not interrelate with the kit in the same way as the numbers interrelated with the band. In *Gulack*, the printed matter would not achieve its educational purposes without the band, and the band without the printed matter would similarly be unable to produce the desired result. Here, the printed matter in no way depends on the kit, and the kit does not depend on the printed matter. All that the printed matter does is teach a new use for an existing product. As the *Gulack* court pointed out, "[w]here the printed matter is not functionally related to the substrate, the printed matter will not distinguish the invention from the prior art in terms of patentability." *Id.* **If we were to adopt *Ngai's* position, anyone could continue patenting a product indefinitely provided that they add a new instruction sheet to the product."**

The CAFC affirmed the Board of Patent Appeals and Interferences (BPAI) and concluded that *Ngai et al.*'s claimed kit was anticipated by the prior art

(the 10X buffer with instructions), despite the fact that Ngai *et al.*'s claim 1 method was distinct from the instructions in the prior art. In fact, the method of claim 1 was determined to be patentable over the prior art. The CAFC further concluded that Ngai *et al.*'s instructions merely taught how to use the reagent component of the kit (the 10X buffer). Specifically, the CAFC concluded:

"All that the printed matter does is teach a new use for an existing product."

and

"He [Ngai] is not, however, entitled to patent a known product by simply attaching a set of instructions to that product."

In the present application the instructions merely teach a different use for a known sealable bag. The applicant's claimed enclosed bag does not depend on the claimed instructions in order to function; i.e., the instructions do not enable the bag to hold a sample. Likewise, the claimed instructions do not depend on the bag in order to instruct someone how to sample. Therefore, the applicant's instructions do not enable any sealable bag from holding any material and only describe a process to store a sample in the bag and then to sample the headspace of the bag.

The applicant's claims for a kit comprising a bag and instructions to use the bag is clearly analogous to Ngai *et al.*'s kit having a known reagent (the 10X buffer) and instructions that taught how to use the reagent. The applicant's arguments with regard to how their instructions are not taught by the prior art, and, therefore, there can be no anticipation are also similar to those proffered

by Ngai *et al.* However, both the BPAI and the CAFC unequivocally and unambiguously disagreed with that argument.

Based on the fact that the applicant's kit is known in the art as evidenced by Hemphill, and further because of the CAFC's decision in *In re Ngai*, the applicant's claimed kit is clearly anticipated under 35 USC 102(b).

Furthermore, the intended use of claims 23-34; e.g., for measuring the volatile organic compounds of a material produced in a (spray bed dryer (claims 23, 26, 29), fluid bed dryer (claims 24, 27, 30), storage tank (claims 25, 28, 31)), is not being afforded any patentable weight. The intended use of the kit does not patentably distinguish the applicant's claims over the prior art. As the applicant is fully aware a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the present application the prior art bags are fully capable of holding materials from a fluid bed dryer, a spray bed dryer, or a storage tank.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 11-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over the applicant's admitted prior art in view of United States Patent 5,140,845 to Robbins, United States Patent 5,809,664 to Legros *et al.*, "Chemical Principles" to Masterton *et al.*, and "Compilation of Air Pollutant Emission Factors, AP-42" to the Environmental Protection Agency (EPA), hereinafter referred to as EPA Method AP-42.

The applicant admits that monitoring and controlling volatile organic compound (VOC) emissions is known. More specifically, the applicant states (emphasis added):

A long-standing problem in the chemically-related manufacturing industry has been the way in which the rate of VOC emissions is controlled and monitored. The concerns associated with VOC control and monitoring are well rooted in governmental policies throughout the world, all of which are aimed at reducing the emission of such VOCs into the atmosphere. Additionally, the manufacturing industries themselves have been notably concerned with safety and environmental concerns associated with VOC emissions. As a result, since the onset of the industrial revolution, the chemically-related manufacturing industry has striven for zero to minimal VOC emissions. To that end, relatively expensive and time-consuming VOC measurement techniques have been developed and have been constantly employed to monitor VOC emissions of virtually every unit operation in every manufacturing facility throughout the world. In fact, numerous companies have sprouted into existence which specialize in testing techniques for VOCs and aid in ensuring compliance with specific strict company as well as governmental regulations. Such specialization and expertise render these services extremely expensive, and therefore, significantly add to the overall expense of whatever product is being manufactured. Accordingly, there remains a need in the art for an inexpensive, less time-consuming, method by which VOCs can be conveniently measured for a given material being produced in a process system.

The admitted prior art teaches that virtually every unit operation in every manufacturing facility throughout the world monitors for VOC emissions. There is no express mention in the admission for monitoring and/or sampling from a fluid bed dryer. The admitted prior art also does not teach holding the

sampled material at a mean exit temperature of the emissions of a process system.

With regard to the first issue it is noted that Legros *et al.* teaches that known that fluid bed dryers can operate up to 400 °C and are a known source of VOCs.

With regard to the second issue Robbins teaches a simple, low cost process for sampling and detecting VOCs. In particular Robbins teaches a process of sampling material from a system, storing the sample in an enclosed bag, sealing the bag, storing the bag until equilibrium is reached in the headspace, and then sampling the headspace in order to determine if VOCs are present. This detection is accomplished using a flame ionization detector (FID). It is known that gas chromatographs and FIDs are used to determine analyte quantities in the sample based on the peak value; i.e., the measured response of the GC/FID. Robbins does not expressly teach a method wherein the sampled material is stored at the mean exit temperature of said emissions of said system.

Masterton *et al.* is cited herein to provide support of the commonly known scientific principles of liquid-vapor headspace equilibrium in a closed system. In Masterton *et al.* a sealed flask is used, however the scientific principles apply equally to a sealed bag. Masterton *et al.* teaches that a liquid placed in the closed system will, over time, reach a state of equilibrium with regard to the headspace. Equilibrium is the state wherein, at any given temperature, the number of molecules from the liquid entering into the vapor

state (into the headspace) equals the number of molecules reentering the liquid state. At higher temperatures a larger fraction of molecules will acquire enough energy to escape from the liquid to the vapor. This means that at higher temperatures more vapor molecules will be present in the headspace than at lower temperatures. Over time a state of headspace equilibrium will be reached. It is just that more molecules will be present in the vapor when equilibrium is reached using higher temperatures.

Furthermore, EPA Method AP-42, §6.8.3.1, states (emphasis added):

The main atmospheric pollution problem in soap manufacturing is odor¹. The storage and handling of liquid ingredients (including sulfonic acids and salts) and sulfates are some of the sources of this odor. Vent lines, vacuum exhausts, raw material and product storage, and waste streams are all potential odor sources. Control of these odors may be achieved by scrubbing exhaust fumes and, if necessary, incinerating the remaining volatile organic compounds (VOC).

In §6.8.3.2 it is also stated (emphasis added):

In addition to particulate emissions, volatile organics may be emitted when the slurry contains organic materials with low vapor pressures. The VOCs originate primarily from the surfactants included in the slurry. The amount vaporized depends on many variables such as tower temperature and the volatility of organics used in the slurry. These vaporized organic materials condense in the tower exhaust airstream into droplets or particles. Paraffin alcohols and amides in the exhaust stream can result in a highly visible plume that persists after the condensed water vapor plume has dissipated.

Opacity and the organic emissions are influenced by granule temperature and moisture at the end of drying, temperature profiles in the dryer, and formulation of the slurry. A method for controlling visible emissions would be to remove offending organic compounds (i.e., by substitution) from the slurry. Otherwise, tower production rate may be reduced thereby reducing air inlet temperatures and exhaust temperatures. Lowering production rate will also reduce organic emissions.

It is quite clear from the teachings of Method AP-42 that process system temperatures are a major causal factor in the amount of VOCs released into the atmosphere. Furthermore, fluid bed dryers (from Legros *et al.*), drying

¹ EPA Method AP-42 refers to odors as VOCs.

towers, vent lines, vacuum exhausts, and waste streams are all regions within a process system whose temperature can be measured.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the teachings of the admitted prior art with the teachings of Robbins, Legros *et al.*, Masterton *et al.*, and EPA Method AP-42 in order to provide a sample of material produced in a process system such as a fluid bed dryer, seal the material in an enclosed bag in order to have a headspace, holding the material at the mean exit temperature of the emissions of the fluid bed dryer in order to allow the headspace to come to equilibrium, and then testing for the presence of VOCs using techniques such as an FID.

First, sampling from a fluid bed dryer would have been obvious since the applicant admits that virtually every manufacturing facility worldwide must monitor for VOCs, and Legros *et al.* teaches that fluid bed dryers are a known source of VOCs. Furthermore, replicating the conditions of the process that creates VOC-containing products; i.e., replicating the temperatures at which VOC-containing products are manufactured or processed would allow one to determine if the process was indeed causing excessive VOCs to be released into the atmosphere. Finally, Robbins teaches a low-cost, simple method and apparatus for detecting VOCs in relatively small samples. One would certainly look to the teachings of Robbins in order to implement an ongoing sampling process that reduces expenses and is also relatively simple to perform. Finally, Robbins clearly addresses this shortcoming noted in the applicant's admitted

prior art; i.e., Robbins clearly shows an inexpensive, less time-consuming process for conveniently measuring VOCs.

With regard to claim 12 the only difference between this claim and claim 11 is the replacement of the term “fluid bed dryer” with “spray bed dryer” as the source of the sampled material. Again, the admitted prior art teaches that virtually every unit operation in every manufacturing facility throughout the world monitors for VOC emissions. Furthermore, EPA Method AP-42 states in §6.8.3.1 that spray bed dryers are a known source of VOCs. One of ordinary skill would be motivated and, more than likely, legally required obtain samples from the spray bed drying process in order to determine the amount of VOCs being released.

With regard to claim 13 the only difference between this claim and claim 11 is the replacement of the term “fluid bed dryer” with “storage tank” as the source of the sampled material. Again, the admitted prior art teaches that virtually every unit operation in every manufacturing facility throughout the world monitors for VOC emissions. Furthermore, EPA Method AP-42 states in §6.8.3.1 that product storage areas; e.g., storage tanks, are a known source of VOCs. One of ordinary skill would be motivated and, more than likely, legally required obtain samples from the storage tank process in order to determine the amount of VOCs being released.

With regard to claims 14-16 Robbins teaches that time is a relevant factor to reach the desired equilibrium in the headspace (column 4, lines 57-58). One of ordinary skill would know to store the material in the enclosed bag

for a time sufficient to reach equilibrium as this would produce a VOC concentration in the headspace that is representative of actual process system operation. The applicant has not providing any evidence, either in the specification or in any response to any office action, that their claimed storage time produces an unexpected or unobvious result over the teachings of the prior art. See *In re Woodruff*, 919 F.2d 1575, 1578 [16 USPQ2d 1934] (Fed. Cir. 1990) ((where “the difference between the claimed invention and the prior art is some range or other variable within the claims..., the [patentee] must show that the particular range is critical, generally by showing that the claimed range achieves unexpected results) and (Courts have long held ... that even though [a] modification results in great improvement and utility over the prior art, it may still not be patentable if the modification was within the capabilities of one skilled in the art, unless the claimed ranges “produce a new and unexpected result which is different in kind and not merely in degree from the results of the prior art.” (quoting *In re Aller*, 220 F.2d 454, 456 [105 USPQ 233] (C.C.P.A. 1955))))).

With regard to claims 17-19 Robbins teaches that the initial mass of the sample is directly related to the measured equilibrium headspace concentration (equation 5, equation 7). One of ordinary skill would know to provide a representative sample size from the process system necessary for reaching equilibrium in the headspace so that the VOC concentration is representative of actual process system operation. See again *In re Woodruff*.

With regard to claims 20-22 one of ordinary skill would choose a temperature that is representative of the specific operating conditions of the process system; e.g., spray bed dryer, fluid bed dryer, storage tank, etc., that is producing VOCs so that the headspace VOC concentration is representative of actual process system operation. See again *In re Woodruff*.

5. Claims 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over the applicant's admitted prior art in view of United States Patent 5,140,845 to Robbins, United States Patent 5,809,664 to Legros *et al.*, "Chemical Principles" to Masterton *et al.*, EPA Method AP-42, United States Patent 5,352,674 to Cummings, and United States Patent 5,174,163 to Gussman *et al.*

The rejection set forth for claims 11-22 is hereby incorporated in its entirety for the rejection of claims 35 and 36.

Claim 35 is directed to the same basic method as claims 11-13 except for the use of a bag having an inner layer and an outer layer. Claim 36 is directed to the same basic method as claims 11-13 except for the use of a bag that does not contribute to the VOC concentration in the headspace.

Cummings teaches that it is known in the art to use foil-lined bags for holding materials for extended periods of time at elevated temperatures. See column 11, lines 15-20. Furthermore, Gussman *et al.* teaches sampling bags are selected based on needs such as strength, abrasion resistance, permeability, and absorbtivity. Gussman *et al.* also teaches that commonly

used sampling bags include those formed of metal foil and plastic. See column 1, lines 7-19.

Official notice is hereby taken that the foil in a foil-lined bag provides for an inert layer that would not contribute to the overall VOC concentration.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the teachings of admitted prior art, Robbins, Legros *et al.*, Masterton *et al.*, and EPA Method AP-42 with the teachings of Cummings and Gussman *et al.* to provide a foil-lined bag for holding a sample so that the bag's overall strength and durability can be increased.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

"Manual for the Certification of Laboratories Analyzing Drinking Water - EPA 815-B-97-001" to the EPA teaches that certified sampling processes require the need for instructions with a kit used for sampling of VOCs. On page IV-3, §5 it is stated:

"All procedural steps in these methods are considered requirements"

Furthermore, §6 states:

"The manner in which samples are collected and handled is critical to obtaining valid data. It is important that a written sampling protocol with specific sampling instructions be available to and used by sample collectors and available for inspection by the certification officer."

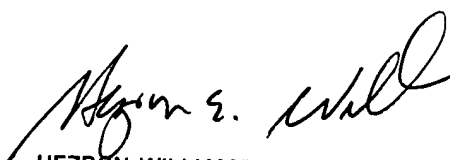
and

"The sample collector should be trained in sampling procedures and have complete written sampling instructions (SOPs) for each type of sample to be collected."

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Rogers whose telephone number is (571) 272-2205. The examiner can normally be reached on Monday - Friday (0730 - 1600). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Hezron E. Williams can be reached on (571) 272-2208. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


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24 May 2006


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